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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/582,059 11/20/00 JACKSON

R 50124/005001

EXAMINER
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HM22/0212

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BOSTON MA 02110

ART UNIT	PAPER NUMBER
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1625

DATE MAILED:

02/12/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/582,059

Applicant(s)

JACKSON ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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1. Claims 1-27 are pending.

### *Specification*

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

### *Claim Objections*

3. Claims 5, 6, 11-14, 17, 19-27 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim because a multiple dependent claim may not be dependent on another multiple dependent claim. See MPEP § 608.01(n)

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 1,
  - the term 'general' is unclear, its deletion is recommended;
  - 'opioid compound' is defined as 'structurally related to morphine' The extent of structural similarity required to be considered "related" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention;
  - 'nitrogen at position 17' has no antecedent basis in formula I;

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- b. Claims 2-4, the substituents on the various groups are not defined.
- c. Claim 7,
  - the term 'general' is unclear, its deletion is recommended;
  - 'opioid-compound' is defined as 'structurally related to morphine' The extent of structural similarity required to be considered "related" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention;
  - the definition for 'YN-' in formula II is confusing; because in addition to 'YN-' of formula IIIa, it also embraces 'Y1-NR4' of formula IIIb;
  - does applicant intend Y1NRR4 (IIIb) to be structurally related to morphine? It is unclear how IIIb, which is not a ring compound, is structurally related to morphine;
  - definition of R1, what does 'H1' mean?
- d. Claim 15, it is improper to refer the compound in the claim as 'the group set out in Table 1'. Chemical compounds should be described by their chemical names or structures.
- f. Claim 16, chemical compounds should be described by their chemical names or structures.
- g. Claim 18,
  - 'opioid-compound' is defined as 'structurally related to morphine' The extent of structural similarity required to be considered "related" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention;
  - 'nitrogen at position 17' has no antecedent basis;
  - it is unclear as to the meaning of the last phrase 'optionally via a spacer group', when a spacer group between the nitrogen and the charged group is recited earlier.

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h. Claim 26 or 27 provides for the use of a compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 26 or 27 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 17-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the exemplified compounds, does not reasonably provide enablement for the other compounds in the generic claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

For the opioid compounds not described in the specification but embraced by the generic claims (see paragraph 4 above), starting materials and the process for preparation of the inventive compounds is not seen but are required. Sources are particularly pertinent especially when the structures of these 'opioid compounds' are not described. Absent sources, the public is offered mere language, rather than enablement. *Ex parte Moersch* 104 USPQ 122. In re Howarth 210.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 7, 18, 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Albertson (4108857). The compound of Example 25 (column 12), its composition and method of use, are encompassed by the instant claims.

8. Claims 1-5, 7, 18, 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Atsumi (3950346). The compound of Example 3 (column 5), its composition and method of use, are encompassed by the instant claims.

9. Claims 1-5, 7, 18, 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokoyama. The compound of RN 70256-52-9, its composition and method of use, are encompassed by the instant claims.

10. Claims 1-5, 7, 18, 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Atsumi (JP 49072261). The compound of RN 54523-96-5, its composition and method of use, are encompassed by the instant claims.

11. Claims 1-5, 7, 18, 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Uwaydah. The compound of RN 70650-78-1, its composition and method of use, are encompassed by the instant claims.

12. Claims 1-5, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Maeda. The compound of RN 77943-85-2 is encompassed by the instant claims.

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13. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hogan (WO 94/01102). The compound of RN 154942-11-7 is encompassed by the instant claims.

14. Claims 1-7, 17-18, 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Jackson. The compound (23) on page 22, its composition and method of use, are encompassed by the instant claims.

*Claim Rejections - 35 USC § 103*

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1-7, 15-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson in view of Greene and/or Scheinmann (5977326).

Jackson teaches that introduction of a polar alkyl guanidino onto the nitrogen atom of the morphine would retain its analgesic effect whilst eliminating its CNS effect (page 18, column 1). A specific example is described on page 22 (compound 23). See paragraph 14 above.

Compound 23 differs from KRS 41 of instant claim 16 in having t-butyl-dimethyl-silyloxy instead of the instant hydroxy..

However, Greene teaches that t-butyl-dimethyl-silyl is a well known protecting group for hydroxy (page 12; page 77). Further, in a morphine compound, Scheinmann teaches that silyl and hydrogen are optional choices for the substituents (column 2, lines 30-31).

At the time of the invention, one of ordinary skill in the art would be motivated to remove the silyl protecting group to obtain the active hydroxy morphine compound to arrive at the instant invention. Further, one of ordinary skill in the art would be motivated to replace

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Jackson's silyl with the alternative hydrogen as taught by Scheinmann to arrive at the instant invention with the reasonable expectation of obtaining an additional morphine compound having analgesic activity without the undesirable CNS effects.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kight can be reached on 703-308-0204. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Evelyn Huang

Primary Examiner

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February 2, 2001